FRANCIS FENWICK, EDWARD SAFRAN, STEVE HARDING, MARY WARDRETT, and LINDA YOUNG, Individually and on behalf of all others similarly situated, *Plaintiffs*, v. RANBAXY PHARMACEUTICALS, INC., RANBAXY LABORATORIES, LTD., RANBAXY LABORATORIES, INC., RANBAXY USA, OHM LABORATORIES, ABC CORPORATIONS 1-10, and JOHN DOES 1-10, *Defendants.*	Civil Action No.: 3:12-cv-07354 (PGS)(DEA) MEMORANDUM AND ORDER

SHERIDAN, U.S.D.J.

This matter is before the Court on a Motion for Class Certification by Plaintiffs Francis Fenwick et al. (ECF No. 138), and a motion to dismiss for lack of standing.

I

This is a class action matter brought by individuals who seek refund of the money paid for certain prescription pills of the drug Atorvastatin, manufactured and sold by the defendants.[1] (Third Amended Compl., ECF No. 47, at ¶ 1, 21). The product is the generic version of Lipitor, and is used to reduce cholesterol. (*Id.* at ¶ 21). On September 5, 2012, Ranbaxy employees noticed blue particles in the raw materials used to manufacture Atorvastatin. (Ranbaxy Docs., ECF No. 124-6, at 2). On October 22, 2012, the particles were identified as glass from glass liners for the reactors used during the manufacturing process for the active pharmaceutical ingredient ("API"), and at that time, Ranbaxy ceased further manufacture and distribution of that API. (*Id.*) The API observed to be containing glass was not distributed to consumers. (*Id.*)

[1] There are a number of defendants named in this action. Plaintiff and defendant both refer to all defendants collectively as Ranbaxy in their briefs. The Court will do the same in this memorandum. It is noted that defendant Daiichi Sankyo Company, Ltd was terminated on January 3, 2013.

Thereafter, Ranbaxy manufactured another batch of the API, in the same facility where it had first noticed the glass in the API. (*Id.*) This batch of API was shipped to a Ranbaxy manufacturing facility in Mohali, India, where it was used in the manufacturing of the Atorvastatin, and was then distributed to the distribution centers of thirty-five different companies. (*Id.*) A total of 41 batches were manufactured and distributed using the API that may have, but was never observed to, contain glass. (*Id.*)

On November 9, 2012, Ranbaxy initiated a voluntary recall at the retail level of 41 lots of Atorvastatin. (*Id.*) Specifically, Ranbaxy recalled lots containing 10mg, 20mg, and 40mg of the product, which were packaged in 90 or 500 count pill bottles. (Ranbaxy Recall Notice, ECF No. 124-7, at 2). Ranbaxy explained it was taking this action "as a precautionary measure due to the fact that we cannot exclude the possibility that the affected lots may contain very small glass particles resembling a fine grain of sand (less than 1 mm in size)." (Ranbaxy Doc., ECF No. 134-4, at 2).

On November 28, 2012, Ranbaxy issued a press release announcing the recall. (*Id.*) Ranbaxy informed consumers that "[b]ased on the current evaluation, the probability of an adverse effect due to consumption of this product is remote" and that consumers "should NOT discontinue taking . . . [the product] without direct guidance from your doctor." (Ranbaxy Helpful Info., ECF No. 134-7, at 2). The recall was classified as a Class II recall by the FDA, meaning "a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." (FDA Correspondence, ECF No. 135-6, at 2). On November 29 and 30, 2012, the FDA issued a statement, notifying the public of the recall. (FDA Statement, ECF No. 136-2, at 2). The FDA advised that the "possibility of advised health problems related

to the recalled [product] is extremely low . . . [and] patients who have the recalled medicine can continue taking it unless directed otherwise by their physician or health care provider." (*Id.*)

The 41 recalled lots amounted to 480,425 bottles containing the recalled Atorvastatin pills. (Pls. Ex. 9, ECF No. 124-12, at 9). Of that amount, 400,201 bottles were returned during the recall. (Final Recall Status Report, ECF No. 136-3, at 18). Nine of the thirty-five companies that received the recalled Atorvastatin pills sold the pills to Class Members. (Pls. Ex. 9, ECF No. 124-12). Plaintiffs allege that from the 90 or 500 count pill bottles, the recalled pills were repackaged and disbursed in smaller bottles, often into 30 count pill bottles, and then sold to consumers through pharmacies. The parties agree that companies do not track the lot numbers when buying or selling drugs to consumers, and thus the parties are unable to determine which consumers received pills from the recalled lots through information provided by the companies. (See Pl. Br., ECF No. 124, at 10; Def. Br., ECF No. 133, at 5). Plaintiffs define a lot number as a number assigned to specific batches of pills, that "identifies exactly when and where a batch of pills was manufactured. Prescription pills of the same type will have different lot numbers if they come from different manufacturing batches." (Pl. Br., ECF No. 124, at 8 n.7). However, plaintiffs state that companies keep record of National Drug Code ("NDC") numbers, which it explains is a product identifier that is "unique, 10 digit, 3 segment number which identifies the manufacturer, the drug type, the dosage, and the number of pills in the bottle [that] the pills are originally shipped in." (*Id.*) Plaintiff's explain that while there were 41 lot numbers identified in the recall, there were only 4 NDC numbers, and consumers can be identified by the NDC numbers. (*Id.*)

Plaintiffs asserts that before Ranbaxy initiated the recall, the recalled pills were received by various distribution centers and "mixed into the inventory pools of pharmacies along with

other pills [not subject to the recall] identified by the 4 NDC numbers." (Pls. Br., ECF No. 124, at 10). Thus, plaintiffs contend that the:

> prescriptions filled for Class Members could have included recalled pills . . . or could have been pills of the exact same type that were not part of the recall . . . The uncertainty about whether the pills dispensed to consumers from those tainted inventory pools makes all of the pills dispersed substandard.

(*Id.*) Accordingly, plaintiffs allege that once the recalled pills were mixed into inventory pools containing non-recalled pills, every pill within that inventory pool became substandard. (*Id.*)[2]

Because the recall was at the retail level, and not at the consumer level, only retailers were required to return the product and, as plaintiff alleges, received a refund. Thus, because consumers were instructed to continue taking the recalled pills, consumers who purchased the recalled pills did not receive a refund. Plaintiffs now seek to certify a class representing consumers who purchased pills that may have contained glass particles. Plaintiffs brought the present action on November 29, 2012, alleging: (1) breach of implied warranty of merchantability; (2) breach of implied warranty of merchantability; (3) breach of express warranty; and (4) unjust enrichment. (*See* Third Amended Compl., ECF No. 47).

II

Class representatives

a. *Fenwick*

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[2] Plaintiffs define "inventory pool" as the inventory of a pharmacy of distribution center. Plaintiffs explain that each part of the chain of distribution has an inventory pool. For example, each company has a distribution center where they received the Atorvastatin pills. At this point on the chain of distribution, plaintiff explains that the recalled pills were mixed into an "inventory pool" of the exact same pills that were not subject to the recall. From the distribution center, the company sends the pills to individual retail pharmacies, which each have their own "inventory pool" of the product. There, plaintiff alleges that the recalled pills and non-recalled pills are further mixed into the pharmacies "inventory pool." It is as this point that the product gets sold to consumers. *See* Pls. Br. at 11-12, 1T9:3 to 10-11.

Francis Fenwick is a New Jersey resident who purchased the product through a CVS Pharmacy in Montvale, New Jersey. When he learned that the product could have been adulterated, he spoke to CVS and was informed that the Defendants conducted a recall on a retail level only. He did not receive a replacement product, and was not refunded the value of the prescription pills. (*Id.* at ¶8).

b. *Safran*

Edward Safran is a Massachusetts resident who purchased Atorvastatin pills through Express Scripts. He reached out to Express Scripts, and he was informed that the product he purchased would not be replaced or refunded. He also did not receive a refund or replacement from Ranbaxy. (*Id.* at ¶9).

c. *Harding*

Steve Harding is a New York resident who purchased Atorvastatin manufactured by Ranbaxy through Express Scripts. Express Scripts informed him that the product he purchased would not be replaced or refunded. Additionally, Ranbaxy did not refund his money, replace the product, or pay him the value of the prescription pills. (*Id.* at ¶10).

d. *Wardett*

Mary Wardett resides in Washington D.C. She purchased Atorvastatin through CVS. Ranbaxy did not refund her money, replace the pills, or pay her the value of the prescription pills. (*Id.* at ¶11).

e. *Young*

Linda Young resides in Texas. She purchased the product through CVS. Ranbaxy did not refund her money, replace the product, or pay her the value of the prescription pill. (*Id.* at ¶12).

While all of the above plaintiffs were initially proposed as possible class representatives, in their current motion, plaintiffs only propose Safran, Harding, and Young as plaintiffs on behalf of the class. *See* infra, part IV, at 17.

III

As a preliminary matter, defendants argue that the present motion should be denied and the complaint dismissed because plaintiffs lack standing to bring these claims. Specifically, Ranbaxy argues that plaintiffs have not suffered a cognizable injury. To have Article III standing, plaintiffs must show that they have "(1) suffered an injury in fact, (2) that it is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial opinion." *Mielo v. Steak 'N Shake Operations, Inc.*, 897 F.3d 467, 478 (3d Cir. 2018) (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016)). In the context of a class action, this Court "focuses solely on the class representative(s)." *Id.* "Putative class members need not establish Article III standing. Instead, the 'cases or controversies' requirement is satisfied so long as a class representative has standing . . . ." *Id.* (quoting *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 362 (3d Cir. 2015)).

Thus, the class representatives must show "an injury in fact" which is a "concrete and particularized invasion of a legally protected interest." *Common Cause of Pa. v. Pennsylvania*, 558 F.3d 249,258 (3d Cir. 2009). In addition, "a plaintiff must also show that his or her injury is 'actual or imminent, not conjectural or hypothetical.'" *Mielo*, 897 F.3d. at 478 (quoting *Spokeo, Inc.*, 136 S. Ct. at 1547). "[R]eview of standing is a threshold inquiry, and that the proper disposition of a case in which the putative class Plaintiffs lack standing is to dismiss the complaint -- not to deny class certification -- and to avoid reaching a decision on the merits of

the claims presented." *Hassine v. Jeffes*, 846 F.2d 169, 176 (3d Cir. 1988). Accordingly, prior to a class being certified, the class representatives must prove standing. *See id.*

Defendant argues that first, plaintiffs cannot represent the original class proposed in the complaint, because there is no evidence that the named plaintiffs have purchased contaminated pills. Second, plaintiffs' theory that they were harmed from the uncertainty of buying potentially contaminated pills from an inventory pool containing both recalled and non-recalled pills also cannot provide standing, because plaintiffs' admitted that if their pills did not contain glass particles, then there was nothing wrong with those pills or the bottles they received. Accordingly, defendants argue that this uncertainty theory is illusory, as consumers could check their individual bottles for the lot numbers that were recalled.

In response, plaintiffs argue that they have standing because they are not claiming that class members may have received substandard pills, rather, they claim that members did receive substandard pills, and as such, there is no uncertainty to their claims. Plaintiffs argue that the following evidence supports that they have standing: the FDA, in a press release, declared the recalled pills "defective" and not in "compliance with the law" because defendants were uncertain of whether they contained glass particles; defendants knowingly distributed those "defective" pills into pharmacy inventory pools; defendants cannot distinguish between the recalled pills and the other pills dispensed from those inventory pools; and "defective" pills that are not "in compliance with the law" cannot be sold and "thus have a market value of zero dollars."

Plaintiffs have standing to move forward in this matter. Requiring testing of each individual pill, as Ranbaxy seemingly proposes, would be unreasonable where Ranbaxy has identified batches of pills in recalled lots that could have been contaminated and plaintiffs

purchased pills from the identified batches. Further, plaintiffs only propose Edward Safran, Steve Harding, and Lina Young as class representatives. Safran and Harding have both established that their purchased pills came from recalled lots, and Young's pharmacist advised her that she purchased a pill bottle from a recalled lot.[3] These named plaintiffs have demonstrated that they have purchased pills from the recalled lots, and thus have standing.

IV

"Class certification is appropriate when the prerequisites of Federal Rule of Civil Procedure 23 are met." *Williams v. Jani-King of Phila. Inc.*, 837 F.3d 314, 318 (3d Cir. 2016). "The class action is 'an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only.'" *Comcast Corp. v. Behrend,* 133 S.Ct. 1426, 1432 (2013) (quoting *Califano v. Yamasaki,* 442 U.S. 682, 700–701 (1979)). To fall within this exception, a party moving to represent a class "must affirmatively demonstrate his [or her] compliance with Rule 23." *Id.* The Third Circuit has emphasized that "actual, not presumed, conformance with Rule 23 requirements is essential." *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 591 (3d Cir. 2012). "The party seeking certification bears the burden of establishing each element of Rule 23 by a preponderance of the evidence." *Id.*

To meet this burden, plaintiffs must satisfy the four prerequisites of Rule 23(a) and show that the action can be maintained under at least one of the three subsections of Rule 23(b). *See Johnston v. HBO Film Mgmt., Inc.,* 265 F.3d 178, 183 (3d Cir. 2001). These four requirements under Rule 23(a) are referred to as numerosity, commonality, typicality, and adequate representation. *Id.* The requirements are "meant to assure both that class action treatment is

[3] Both Harding and Safran determined they purchased recalled pills by identifying the lot numbers on the pill bottles, while Harding's pharmacist informed her that her bottle "matched the batch number in the recall." *See* Harding Dep., ECF No. 135-7, at 100:21-25; Safran Dep. ECF No. 134-9, at 30:21 to 31:1.

necessary and efficient and that it is fair to the absentees under the particular circumstances." *Baby Neal v. Casey,* 43 F.3d 48, 55 (3d Cir. 1994).

Most importantly, a plaintiff seeking certification of a class must "prove by a preponderance of the evidence that the class is ascertainable," pursuant to Rule 23(b)(3). *See Byrd v. Aaron's Inc.,* 784 F.3d 154, 163 (3d Cir. 2015). The class "must be currently and readily ascertainable based on objective criteria." *Marcus*, 687 F.3d at 593. "Ascertainability functions as a necessary prerequisite (or implicit requirement) because it allows a trial court effectively to evaluate the explicit requirements of Rule 23. In other words, the independent ascertainability inquiry ensures that a proposed class will actually function as a class." *Id.* at 162. "The ascertainability inquiry is two-fold, requiring a plaintiff to show that: (1) the class is 'defined with reference to objective criteria'; and (2) there is 'a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.'" *Id.* at 163 (quoting *Hayes v. Wal-Mart Stores, Inc.,* 725 F.3d349, 355 (3d Cir. 2013)). "The ascertainability requirement consists of nothing more than these two inquiries. And it does not mean that a plaintiff must be able to identify all class members at class certification—instead, a plaintiff need only show that class members *can* be identified." *Byrd*, 784 F.3d at 16. Finally, "[a]lthough some evidence used to satisfy ascertainability, such as corporate records, will actually identify class members at the certification stage, ascertainability only requires the plaintiff to show that class members *can be identified* . . . Accordingly, there is no records requirement." *Id.* (quoting *Carrera v. Bayer Corp.*, 727 F.3d 300, 307-08 (3d Cir. 2013)). However, "a party cannot merely provide assurances to the district court that it will later meet Rule 23's requirements . . . [n]or may a party 'merely propose a method of ascertaining a class

without any evidentiary support that the method will be successful.'" *Id.* (quoting Carrera, 727 F.3d at 306, 311).

"Administrative feasibility means that identifying class members is a manageable process that does not require much, if any, individual factual inquiry." *Carrera v. Bayer Corp.*, 727 F.3d 300, 307-08 (3d Cir. 2013). "If class members are impossible to identify without extensive and individualized fact-finding or 'mini-trials,' then a class action is inappropriate." *Marcus*, 687 F.3d at 593. In evaluating a motion for class certification, a court must "probe behind the pleadings when necessary and conduct a 'rigorous analysis' in order to determine whether the Rule 23 certification requirements are satisfied." *Id.* This "'rigorous analysis" applies with equal force to the ascertainability inquiry. *Id.*

Plaintiffs seek class certification based upon the following class definition:

> All consumers who were dispensed Ranbaxy Atorvastatin pills identified by found NDC numbers (66304-827-90; 66304-829-90; and 66304-829-05) by certain pharmacies and mail order facilities during specific date ranges. Class Members were dispensed pills from inventory pools that included recalled pills for the exact same type that possibly contained glass particles. The Class Periods are the date ranges that those inventory pools included some of the recalled pills. The class excluded any consumers who are known with certainty to have received pills that were not from the recalled lots.

(Pl. Br. at 4). Plaintiffs also provide a more detailed, alternative definition:

> All consumers who were dispensed Ranbaxy Atorvastatin pills identified by found NDC numbers (66304-827-90; 66304-828-90; 66304-829-90; 66307-829-05) from a list of specified stores of seven retail pharmacy companies or from a list of specified dispensing facilities of two mail order pharmacy companies during specific date ranges. Ranbaxy recalled 41 lots of pills identified by those found NDC numbers because of possible contamination with glass particles. Class Members were dispensed pills from inventory pools of each of the specified retail pharmacy stores included the recalled pills and the date ranges that the inventory pools of each of the specified retail pharmacy stores included the recalled pills and the date ranges that the inventory pools of each of the specified mail order dispensing facilities included the recalled pills. The class excludes any consumers who are known with certainty to have received pills that were not from the recalled lots.

(Pl. Br., ECF No. 124, at 5 n.2).

The second, more detailed definition, is analyzed here. Plaintiffs also propose using sub-classes to organize the class members by the companies that dispensed the pills to each consumer.

Here, plaintiffs argue that the class definition is clear and refers to objective criteria to describe class members, and that the class is readily ascertainable as it has identified a mechanism for identifying class members. To determine ascertainability, plaintiffs rely upon the methodology developed by Gary L. French, a consulting economist and Senior Advisor to Natham Associates, Inc. French submitted a damages report on October 30, 2017 that highlighted the methodology as applied to individuals who were dispensed the recalled pills from a sample inventory pool of four of the nine retail pharmacy companies. (Pl. Ex. 12, ECF No. 124, ¶ 7). Plaintiffs aver that:

> [t]he discovery, investigation, and non-party discovery in the case enables us to track the recalled Ranbaxy pills into the inventory pools of the nine companies which dispensed pills to Class Members. Using the information and data from those nine companies, we can identify the consumers who were dispensed pills from their inventory pools on dates that those inventory pools were tainted with recalled Ranbaxy pills.

(Pl. Br., ECF No. 124, at 15-16). Specifically, plaintiffs' expert explained that the method for ascertaining damages can be applied to identifying class members. Plaintiffs' expert's methodology identifies a timeframe during which pills that came from an inventory pool containing both recalled and non-recalled pills were sold to customers. (Pl. Expert Cert., ECF No. 138-1, at ¶ 6). The timeframe is sorted by pharmacy and NDC number. Plaintiffs' expert explained that he first began with the earliest date that distribution centers received recalled lots, then determined when the distribution centers transferred these pills over to their store inventories, and finally was able to determine the earliest date, by NDC number, that the pills

from inventory lots containing both recalled and non-recalled pills were available for sale to consumers. (*Id.*) The end date for the time frame is the date of defendants' recall notice. (*Id.* at ¶ 7).

Based on reviewing the sales made within these time frames, plaintiffs' expert claims that this methodology can not only identify damages, but is also able to identify: (1) the inventory pools that included recalled pills; (2) the class members who were recieved pills from inventory pools that included recalled and non-recalled pills, (3) the date that the Class Member received the pills; (4) the pharmacy that dispensed the pills; (5) the quantity, dosage, and NDC numbers of the pills dispensed to each class member; and (6) the amount paid for the pills. Further, plaintiffs claim that this methodology was used to determine that there were 960,873 prescriptions filled from inventory pools containing both recalled and non-recalled pills. (*Id.* at ¶ 2). In response, defendants argue that plaintiffs provide only assurances that they can identify class members, and "virtually no evidence of ascertainability." (Defs. Br., ECF No. 133, at 16). Defendants assert that the methodology applied by French does not provide a mechanism for identifying class members, because French opined on damages and not ascertainability, the model is based on a sample of only four companies, it does not include consumer-level data for most of the companies that sold recalled pills, the data that French relied upon did not identify any consumers or individual purchasers, and because this methodology model includes consumers who bought the pills from non-recalled lots. (*Id.* at 17).

The method for class certification proposed by plaintiffs is insufficient for ascertaining all of the members of the proposed class. As such, it does not show that class members can actually be identified. Plaintiffs rely primarily on NDC numbers and the chain of distribution to identify potential class members that may have purchased pills from inventory pools that may have

contained recalled pills. However, the NDC numbers, while containing information about the type of drug or medication the pills contain, the pills' manufacturer, and the specific dosage of each pill, do not contain any information or means to identify what batch the pills came from. This means that the NDC numbers are unreliable for use in determining class members, as these numbers do not identify if the pills purchased were part of an inventory pool containing both recalled pills and non-recalled pills, or if the pills came from an inventory pool containing only non-recalled pills. Identifying potential class members by lot number is far more reliable, because lot numbers identify exactly what batch the pills came from, and if the pills came from a recalled batch. Plaintiffs argue that this does not present a barrier to class certification, as once the recalled pills were mixed into inventory pools containing non-recalled pills, every pill within that inventory pool became substandard, and propose using the NDC numbers and the chain of distribution to identify potential class members. For this to be an effective means of ascertaining potential class members, plaintiffs would need information about the chain of distribution, including: (1) information regarding when Ranbaxy transferred the recalled pills to each company's distribution center; (2) data on when those recalled pills were mixed into inventory pools containing non-recalled pills; (3) data on when those pills (both recalled and non-recalled) were transferred to pharmacy stores; (4) data on when those pills were sold to consumers; and (5) a means to identify consumers. Information on the chain of distribution is necessary because it shows if and when distribution centers sent pills from an inventory pool containing both recalled and non-recalled pills, and if and when those pills were sold to consumers. Plaintiffs have not shown that the data they have provided includes this necessary information.

The methodology suggested by plaintiffs does not show that potential class members can be identified, as plaintiffs' have not shown that this method will be successful. Plaintiffs

have provided the court with data compiled by eight different companies, and argue that this data, in conjunction with the suggested methodology, shows that class members can be identified. There are seven retail pharmacies, and two mail order pharmacies that need to provide their consumer level data in order to ascertain individual class members. These companies are Rite Aid Headquarters Corp. ("Rite Aid"), The Kroger Co. ("Peytons/Kroger"), CVS Pharmacy Inc. ("CVS"), Winn Dixie, Osborn Drugs, Discount Drug Mart, Inc., SuperValue Inc. ("SuperValue"), Express Scripts, Inc./Medco Health Solutions ("Express Scripts/Medco"). Plaintiffs have provided the Court with definitive data on when Ranbaxy transferred the recalled pills to each company's distribution center. (*See* ECF 143). However, the following has not been provided by every company, nor has plaintiffs indicated that it is possible to provide the following: data on when those recalled pills were mixed into inventory pools containing non-recalled pills; data on when those pills (both recalled and non-recalled) were transferred to pharmacy stores; data on when those pills were sold to consumers; and data on the identification of those consumers.

For example, only Express Scripts/Medco has provided data identifying consumers that received pills from recalled lots. (*See* ECF No. 143-1, at 3 to 5). In contrast, Rite Aid and Winn Dixie have identified potential class members by names and addresses, the NDC numbers confirming they purchased the product, the date of the purchase, the dates that it received recalled pills to its distribution centers, and the dates it sent those pills to its pharmacy stores. (*See* ECF No. 143-1, at 15-16, 33-34). However, this information does not show whether or not these individuals purchased pills from an inventory pool containing both recalled and non-recalled pills. (*Id.* at 15-16, 33-34). Similarly, while SuperValue has identified potential class members by names and addresses, the NDC numbers confirming they purchased, the date the

prescription was filled, it does not include any information on when it sent pills from its distribution centers to its stores. (*Id.* at 37-38).

Kroger/Peyton has similarly provided data regarding the stores it shipped pills to, identified by the NDC number during the recall dates, but not by lot number, so it is not clear if it shipped any recalled pills. (*Id.* 18-19). Kroger/Peyton attests that it can provide the "name and contact information" later, by agreement by the parties. (*Id.*) Here, the data Kroger/Peyton has supplied is insufficient, as it does not identify if the pills it later distributed from its inventory pools contained recalled pills; thus that important link in the chain of distribution is missing. Further, the data provided by Discount Drug Mart Inc. does not contain information on when its distribution centers, after receiving the pills, sent the pills to its stores, and if the pills it sent to stores contained pills from an inventory pool of both recalled and non-recalled pills; instead, it identifies potential class members based on the date it sold the product to those consumers. (*Id.* at 42).

To further highlight the difficulty in identifying potential class members, the data sets provided by CVS and Osborn are especially problematic. The consumer and sales data plaintiffs provided for CVS did not provide comprehensive information in tracing the contaminated product to each individual proposed class member. (*Id.* at 23-24). CVS has provided only the relevant NDC numbers, and the date that CVS pharmacies received the product at its individual stores from its distribution centers. (*Id.*). It does not include any information identifying consumers or when consumers purchased the product, and does not include any information that may help identify potential class members. (*Id.*) The information provided by CVS show that class members can be identified because it fails to trace the recalled Ranbaxy Atorvastatin pills identified by the NDC numbers to specific individual customers, and fails to show that the pills

distributed by CVS to its stores contained both recalled and non-recalled product. Further, CVS did not track data regarding the lot numbers contained in shipments of the product to CVS distribution centers or to CVS retail stores, so its information is insufficient to show which CVS stores received the affected product during the time of the recall. Similarly, the information plaintiffs provided for Osborn lists only the consumer's doctors who prescribed the product for their patients, and does not identify individual consumers that could be part of the class. (*See* ECF 143-2). The data only supplies information about when Osborn shipped the product from the distribution center to the its individual pharmacies, and the date the prescription was filled. (*Id.*)

Plaintiffs suggested that the methodology to determine members of the class included the "quantity, dosage, and NDC numbers of the pills dispensed to each Class Member," but it is evident here that a process for reliably identifying potential class members has not been identified. It is not enough to show that distribution centers received recalled pills; instead plaintiffs must identify a methodology that identifies which consumers purchased pills from an inventory pool containing both recalled and non-recalled pills. Here, the type and extent of information provided by plaintiffs regarding when the companies shipped the product from inventory pools containing both recalled and non-recalled pills from their distribution centers to individual store pharmacies, when those pharmacies sold the product to consumers, and who the pills were sold to varies greatly. As a result, the methodology supplied by plaintiffs fails to show that class members can be identified, and simply "propose[s] a method of ascertaining a class without any evidentiary support that the method will be successful." *Byrd*, 784 F.3d at 16.

Plaintiffs' expert proposed that 960,873 prescriptions were filled with Ranbaxy Atorvastatin pills dispensed from inventory pools that included both recalled and non-recalled

pills, but the unresolvable issue here is that the plaintiffs cannot ascertain all members of its proposed class for this action, as they cannot show which potential class members received pills from an inventory pool containing recalled and non-recalled pills. Because the Class cannot be ascertained, plaintiffs' Motion for Class Certification cannot be granted. The fact that Ranbaxy delivered potentially contaminated Atorvastatin to nine different pharmaceutical companies, who later may have sold those pills to their consumers, in and of itself does not definitively show that each member of the class received recalled pills, or received pills from an inventory group containing both recalled and non-recalled pills.

Finally, even if plaintiffs were able to identify potential class members from the methodology they have suggested, this methodology does not suggest a means for determining consumers who did not purchase recalled pills, and thus are not included in the class. As a result, the proposed class would include within it consumers who did not purchase any recalled pills, which its own proposed definition expressly excludes. (Pl. Br., ECF No. 124, at 5 n.2). However, as made clear during discovery, it is likely impossible to determine which consumers "are known with certainty to have received pills that were not from the recalled lots." *Id.* Of the five initial named plaintiffs, only three remain. The bottles distributed by Ranbaxy to retailers were not part of an inventory pool process, and instead these bottles were sent directly to the customer by the retailer. For instance, during discovery, an examination of Fenwick's pill bottle revealed that the lot number on his bottle did not match any of the recalled lots thus he did not receive any recalled pills. (Fenwick Dep., ECF No. 134-11; 170:2 to 171:15). Similarly, it was later determined that Wardett purchased her pill bottle before any recalled product could be distributed to CVS. (Wardett Dep., ECF No. 136-5, 186:14 to 187:9).

Here, it is impossible to identify potential class members without extensive and individualized fact-finding or mini-trials. Like in *Marcus*, none of the records and data provided from the companies show or can show which individuals should be included in the proposed class, as most of the data provided fails to show which potential class members received pills from an inventory pool containing recalled and non-recalled pills, and many records even failed to identify specific class members. *See Marcus*, 687 F.3d at 593. Further, it is likely impossible to, several years after the recall, determine who from the potential class members did not purchase recalled pills, as the companies did not track the lot numbers. As plaintiffs' expert agreed, the methodology proposed would include members who indisputably did not buy the recalled product. (Dep. Of French, ECF No. 136-9, 148:3-22; 156:7-12). Plaintiffs' expert also agreed that there is "likely no feasible way to accurately identify" individuals who actually bought the recalled product. (*Id.* at 179:9-13). Thus, plaintiffs have failed to show by a preponderance of the evidence that the methodology suggested will be successful in identifying potential class members. Accordingly, the Court finds that plaintiffs have failed to demonstrate by a preponderance of the evidence that they can identify class members based on its proposed methodology. Accordingly, the Court is unable to grant plaintiffs' motion for class certification.

V.

Class certification must also satisfy the requirements of Rule 23(b), specifically here, the predominance and superiority requirements of Rule 23(b)(3). Because the "predominance criterion is far more demanding" than Rule 23(a)'s requirements, the Court will address predominance first. *See Amchem Prods. v. Windsor*, 521 U.S. 591, 624, 117 S. Ct. 2231, 2250 (1997). Predominance requires "that questions of law or fact common to the members of the class predominate over any questions affecting only individual members." Fed. R. Civ. P.

23(b)(3). To assist courts in analyzing cases for predominance and superiority, Rule 23(b)(3) includes a nonexclusive list of relevant factors to consider, including: "(A) the class members' interests in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (D) the difficulties likely to be encountered in the management of a class action." *Id.*

The "predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1045 (2016). The Supreme Court has explained that courts must give "careful scrutiny to the relation between common and individual questions in a case." *Id.* "An individual question is one where members of a proposed class will need to present evidence that varies from member to member, while a common question is one where the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof." *Id.* Overall, "issues common to the class must predominate over individual issues, and the class action device must be superior to other means of handling the litigation." *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 186 (3d Cir. 2001).

Ranbaxy argues that common legal issues do not predominate, because the laws of the 50 states would apply to this class. In response, plaintiffs' argue that for all three causes of action, the law of New Jersey should be applied, as New Jersey has the greatest interest and the parties have applied New Jersey law thus far in the litigation. "There may . . . be circumstances . . . where [i]n a multi-state class action, variations in state law may swamp any common issues and defeat predominance." *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 180 (3d Cir. 2014)

(quotation omitted). Thus, "[a] necessary precondition to deciding Rule 23 issues is a determination of the state whose law will apply." *Powers v. Lycoming Engines*, 328 F. App'x 121, 124 (3d Cir. 2009). The court in *Powers* explained that in nationwide classes:

> attempts to structure and certify nationwide classes involving plaintiffs in all fifty states often turn on whether the law of a single state or multiple states should be applied. Irreconcilable conflicts can be an impediment to certification because they can offset the analysis of the legal commonality, typicality, and adequacy requirements of Rule 23(a), and the superiority and predominance factors of Rule 23(b)(3). For example, we have observed that nationwide class action movants must credibly demonstrate, through an "extensive analysis" of state law variances, "that class certification does not present insuperable obstacles." *In re Sch. Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir. 1986). This comprehensive analysis is necessary because aggregate class action should not alter the applicable substantive legal rights of the plaintiffs. *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 821 (1985) (constitutional limitations on choice of law apply even in nationwide class actions); *see also Amchem Prods.*, 83 F.3d at 627 (court must conduct an "individualized choice of law analysis to each plaintiff's claims" even in nationwide class actions).

Powers v. Lycoming Engines, 328 F. App'x 121, 124 (3d Cir. 2009).

Because federal courts apply the choice-of-law principles of the forum state, New Jersey choice-of-law rules apply. *See Chin v. Chrysler LLC*, 538 F.3d 272, 278 (3d Cir. 2008). New Jersey applies the most significant relationship test as set out in the Restatement (Second) of Conflict of Laws. *See Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 180 (3d Cir. 2014); *P.V. ex rel. T.V. v. Camp Jaycee*, 962 A.2d 453, 460 (2008). Courts must first "determine whether an actual conflict exists" by "examining the substance of the potentially applicable laws to determine whether there is a distinction between them." *Camp Jaycee*, 962 A.2d at 460. Next, "[w]ith an actual conflict, courts must then determine, by reference to the Restatement, which state has the most significant relationship to the case and parties." *Grandalski*, 767 F.3d at 180 (citing *Camp Jaycee*, 962 A.2d at 461). "In the class certification context, if the court determines that the laws of numerous states would apply to the prospective class, plaintiffs bear

the burden of providing an extensive analysis of state law variations to determine whether there are insuperable obstacles to class certification." *Payne v. FujiFilm U.S.A., Inc.*, No. 07-385, 2010 U.S. Dist. LEXIS 52808, at *19-20 (D.N.J. May 28, 2010) (quotation omitted).

The Court first determines whether an actual conflict exists between the laws of New Jersey and the laws of the fifty states regarding breach of express and implied warranty. Plaintiffs first argue that New Jersey law applies because it is the law that has been applied to this case thus far. Plaintiffs further argue that this Court previously found, for purposes of a motion to dismiss, that there was a "sufficiently direct relationship" between consumers and defendants, thus based on this, the Court can: (1) certify the class because, regarding breach of implied warranty, "the only substantial difference among state laws on those claims is whether privity is required" and (2) certify the class because the only issue affecting the express warranty claims is reliance, which they claim is not an issue in this case. (Pl. Reply Br., ECF No. 137, at 16). In support of these arguments, plaintiffs provide the Court with two charts that portray the textual similarities between each states' breach of express warranty or breach of implied warranty statute. (*See* Pl. Exs. 17, 18, ECF Nos. 124-20, 124-21). First, regarding this Court's previous finding regarding that there was a "sufficiently direct relationship" between consumers and Ranbaxy, that finding was in the context of a motion to dismiss, where the Court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). In contrast, here, plaintiffs bear the burden of establishing each element of Rule 23 by a preponderance of the evidence." *Marcus*, 687 F.3d at 591.

Moreover, the court in *Cole v. GMC*, 484 F.3d 717 (5th Cir. 2007), was presented with similar forms of support for the plaintiffs' claims that the legal issues for express and implied warranty were predominant, and concluded that plaintiffs did not meet their burden of demonstrating predominance because they "failed both to undertake the required 'extensive analysis' of variations in state law concerning their claims and to consider how those variations impact predominance." *Cole*, 484 F.3d at 725. The court explained that "Plaintiffs' largely textual presentation of legal authority oversimplified the required analysis and glossed over the glaring substantive legal conflicts among the applicable laws of each jurisdiction." *Id.* at 725-56.

Plaintiffs have done exactly the same here. Courts have found that actual conflicts exist between the contract laws of New Jersey and other states, explaining "State laws regarding breach of express and implied warranty . . . differ greatly with regard to '(1) whether plaintiffs must demonstrate reliance, (2) whether plaintiffs must provide notice of breach, (3) whether there must be privity of contract, (4) whether plaintiffs may recover for unmanifested . . . defects, (5) whether merchantability may be presumed and (6) whether warranty protections extend to used [goods].'" *Payne*, 2010 U.S. Dist. LEXIS 52808, at *27 (quoting *Cole*, 484 F.3d at 726). Plaintiffs have not explained how these variations in state law for express and implied contract claims are not "insuperable obstacles to class certification." *Payne*, 2010 U.S. Dist. LEXIS 52808, at *20.

Because there is an actual conflict, the Court will apply Section 188 of the Restatement (Second) of conflict laws. *See Jackson v. Midland Funding Ltd. Liab. Co.*, 468 F. App'x 123, 126 (3d Cir. 2012); *Payne*, 2010 U.S. Dist. LEXIS 52808, at *29; *Agostino v. Quest Diagnostics Inc.*, 256 F.R.D. 437, 464 (D.N.J. 2009). As one court has explained, "[i]n determining which state law has the most significant relationship, the analysis under Section 188 requires the court

to consider: '(1) the place of contracting, (2) the place of negotiation of the contract, (3) the place of performance, (4) the location of the subject matter of the contract, and (5) the domicile, residence, nationality, place of incorporation and place of business of the parties." *Agostino,* 256 F.R.D. at 464; *see Restatement (Second) of Conflict of Laws § 188* (1971).

Plaintiffs argue that New Jersey has the greatest interest and most significant contacts with New Jersey, because Ranbaxy's headquarters are located in New Jersey, the recall occurred at its New Jersey laboratory, the recall was managed from Ranbaxy's New Jersey headquarters, Ranbaxy reported to the FDA office in New Jersey, and Ranbaxy made "promises" to consumers from New Jersey that the product was of the same quality, safety and purity as generic Lipitor. (Pl. Br. at 34-34). However, analyzing the factors discussed above, each individual potential class member's home state has the most significant relationship to plaintiffs' contract claims. The sale of the pills occurred throughout the country, in many different states. Like in *Payne*, plaintiffs' claims of express and implied breach of warranty occurred when the prospective class members purchased the pills from individual pharmacies in their home states.

Because the place of contracting, negotiation of the contract, performance of the contract, and the subject matter of the contract occurred in each individual prospective class member's home state, the home state has a significant relationship with the individual prospective class member. Accordingly, the laws of each individual class member's home state apply for plaintiffs' breach of express and implied warranty claims.

The Court next determines whether an actual conflict exists between the laws of New Jersey and the laws of the fifty states regarding plaintiffs' unjust enrichment claims. Plaintiffs argues that this Court can certify the class because "the only substantial difference among State laws on unjust enrichment is the 'sufficiently direct relationship' issue." (Pl. reply Br., ECF No.

137, at 16). Plaintiff has not provided any extensive analysis on the variations of state laws regarding unjust enrichment. Regardless, many courts have determined that "unjust enrichment laws do not vary in any substantive manner from state to state." *Snyder v. Farnam Cos.*, 792 F. Supp. 2d 712, 723 (D.N.J. 2011) (citing *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 58 (D.N.J. 2009); *Agostino v. Quest Diagnostics Inc.*, 256 F.R.D. 437, 464 (D.N.J. 2009); *Pa. Employee, Benefit Trust Fund v. Zeneca, Inc.*, 710 F. Supp. 2d 458 (D. Del. 2010); *Powers v. Lycoming Engines*, 245 F.R.D. 226, 231 (E.D. Pa. 2007)). Accordingly, because there exists no conflict, New Jersey law will be applied to all plaintiffs' unjust enrichment claims.

In summary, regarding plaintiffs' breach of express and implied warranty claims, the laws differing laws of the fifty states would apply. Regarding plaintiffs' unjust enrichment claims, the law of New Jersey would apply. Plaintiff has not provided any extensive analysis of the state law variances for the breach of express and implied warranty claims, and whether or how these variances may impact predominance. Accordingly, because common legal issues do not predominate, plaintiffs have not satisfied the predominance requirement of Rule 23(b)(3). Thus, based on the information provided, the Court is unable to grant Plaintiffs' motion for class certification.

Conclusion

Plaintiffs' motion for class certification is DENIED.

ORDER

This matter, having been brought before the Court on plaintiffs' for class certification [ECF No. 124], and the Court having considered the briefs and submissions of the parties; and having heard oral argument; and for good cause having been shown;

IT IS on this 13 day of November, 2018;

ORDERED that Plaintiffs' motion for class certification (ECF No. 124) is DENIED.

Peter G. Sheridan

PETER G. SHERIDAN, U.S.D.J.